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MAY 2 3 2003

# 510(k) SUMMARY
# Safety and Effectiveness Summary

## Pathway STM-10 Pelvic Floor Stimulator

**Submitted by:**

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**Contact Person:**

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**Date Submitted:**
April 7, 2002

## NAME OF DEVICE

Trade name: Pathway STM-10 Pelvic Floor Stimulator
Common name: Non-implanted Electrical Continence Device
Classification name: 78 KPI, ClassII, (876.5320)

## IDENTIFICATION OF PREDICATE DEVICE

The device to which we claim substantial equivalence is the Pathway CTS 2000 K023906 manufactured by The Prometheus Group.

## DESCRIPTION OF DEVICE

The Pathway STM-10 is used to stimulate the pelvic floor muscles for the treatment of incontinence. The Pathway Vaginal or Anal EMG/Stim perineometer sensor is connected to the Pathway STM-10 device to provide stimulation to the patient. This assists the patient with muscle contractions.

The Pathway STM-10 uses Pathway EMG/Stim Perineometer Sensors which are single-user sensors. The patient inserts the sensor into the vagina or rectum and uses the Pathway STM-10 to electrically stimulate the pelvic floor muscles to assist the contraction. The aim is to improve the strength and control of the pelvic floor muscles.

## INTENDED USE

***Indications For Use:***

* **Urinary Incontinence : Stress, Urge and Mixed Incontinence**
* **Neuromuscular Reeducation**

# SUMMARY OF TECHNICAL CHARACTERISTIC COMPARISON TO PREDICATE DEVICE

| Parameter | Pathway STM-10 | Pathway CTS 2000 |
|---|---|---|
| Intended Use | Treatment of Urinary Incontinence; Neuromuscular Reeducation | Treatment of Urinary Incontinence; Neuromuscular Reeducation |
| Stimulator Output | 0-60 mA | 0-100 mA |
| Waveform | Asymmetrical Balanced Pulsed Current | Asymmetrical Balanced Pulsed Current |
| Charge/pulse at 500 ohms | 17uC | 28uC |
| Frequency | 12.5, 50 100, 200Hz | 12.5, 50, 100, 200 Hz |
| Peak pulse intensity | 60 mA | 100 mA |
| Pulse width | .3 ms fixed | .3 ms fixed |
| Ramps | 2 sec on ramp, one sec off ramp | 2 sec on ramp, one sec off ramp |
| Duty Cycle | Work/Rest of 5 seconds on, 5 seconds off (5/5), 5/10, 10/10, 10/20. | Work Time: 1 – 60 Seconds<br>Rest Time: 0 - 60 Seconds |
| Session Duration (min) | 5, 10, 15, 20, 25, or 30. | 0-60 |
| Programmable features | None by Patient; Frequency, Duty cycle, Session length by physician | None by Patient; Frequency, Duty cycle, Session length by physician |
| Vaginal EMG/Stim Probe Used | Pathway Vaginal EMG/Stimulation Sensor K993976 | Pathway Vaginal EMG/Stimulation Sensor K993976 |
| Anal EMG/Stim Probe Used | Pathway Anal EMG/Stimulation Sensor K993976 | Pathway Anal EMG/Stimulation Sensor K993976 |
| Vaginal EMG/Stim probe electrode surface area: | 2.31 $cm^2$ | 2.31 $cm^2$ |
| Anal EMG/Stim probe electrode surface area: | 2.12 $cm^2$ | 2.12 $cm^2$ |
| Current Density (full output @ 500 ohms) | Pathway Vaginal EMG/Stim Sensor: 26.0 $mA/cm^2$<br>Pathway Anal EMG/Stim Sensor: 28.3 $mA/cm^2$<br>(Max. Instantaneous) | Pathway Vaginal EMG/Stim Sensor: 43.3 $mA/cm^2$<br>Pathway Anal EMG/Stim Sensor: 47.2 $mA/cm^2$<br>(Max. Instantaneous) |
| Power Density (full output @ 500 ohms) | Pathway Vaginal EMG/Stim Sensor: 5.6 $mW/cm^2$<br>Pathway Anal EMG/Stim Sensor: 6.1 $mW/cm^2$<br>(maximum intensity, .3ms pulse width, 200Hz) | Pathway Vaginal EMG/Stim Sensor: 15.6 $mW/cm^2$<br>Pathway Anal EMG/Stim Sensor: 17.0 $mW/cm^2$<br>(maximum intensity, .3ms pulse width, 200Hz) |

## BENCH TEST DATA

A series of bench tests were performed using the Pathway STM-10 to show the device accurately applies stimulation and is substantially equivalent to the predicate device. The Pathway STM-10 was used to apply programmed stimulation outputs and the resulting waveforms were measured and compared to the intended signals.

The bench tests show the Pathway STM-10 accurately applies muscle stimulation.

## BIOCOMPATIBILITY TESTING

The Pathway Vaginal EMG/Stimulation Perineometer Sensor and the Pathway Anal EMG/Stimulation Perineometer Sensor have been laboratory tested for the safety of the materials. The Pathway Perineometer Sensors were found to be safe under the standards required for each test.

## CONCLUSION

The Pathway STM-10 is safe and effective for its intended use. The Pathway STM-10 is substantially equivalent to the predicate device.

## END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2003

Mr. Peter A. Sullivan
Engineer
The Prometheus Group
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DUXBURY MA 02332

Re: K030039
Trade/Device Name: Pathway STM-10
Pelvic Floor Stimulator
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical
continence device
Regulatory Class: II
Product Code: 78 KPI
Dated: April 7, 2003
Received: April 9, 2003

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K030039

SECTION 2 - STATEMENT OF INDICATIONS FOR USE

## 2.1 STATEMENT OF INDICATIONS FOR USE

510(k) Number: K030039
Device Name: Pathway STM-10 pelvic floor stimulator

## Indications for Use:

*Indications For Use*

* **Urinary Incontinence : Stress, Urge and Mixed Incontinence**
* **Neuromuscular Reeducation**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-the-Counter Use: _____
(Per 21 CFR 801.109)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030039